WHITE & CASE LLP
Bryan A. Merryman (SBN 134357)
bmerryman@whitecase.com
555 S. Flower Street, Suite 2700
Los Angeles, CA 90071-2433
Telephone: (213) 620-7700
Facsimile: (213) 452-2329

WILLIAMS & CONNOLLY LLP
Joseph G. Petrosinelli (Admitted *Pro Hac Vice*)
jpetrosinelli@wc.com
Neelum J. Wadhwani (SBN 247948)
nwadhwani@wc.com
680 Maine Avenue S.W.
Washington, D.C. 20024
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant
GERBER PRODUCTS COMPANY

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE: BABY FOOD PRODUCTS LIABILITY LITIGATION This Document Relates to: ALL ACTIONS	Case No. 24-md-3101-JSC MDL 3101 Hon. Jacqueline Scott Corley **DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN TESTIMONY FROM DEFENDANTS' EXPERT WITNESSES UNDER FRCP 26 AND FRE 702** Date: December 8, 2025 Time: 9:00 a.m. PT Location: Courtroom 8 19th Floor 450 Golden Gate Ave. San Francisco, CA 94102

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INTRODUCTION

Plaintiffs' Motion seeks to exclude certain opinions offered by eight of Defendants' eleven experts: Dr. Elise Robinson, Dr. Stephan Sanders, Dr. William Banner, Dr. Matthew State, Dr. Eric Fombonne, Dr. Shannon Kelleher, Dr. Deirdre Tobias, and Dr. Gabriel Filippelli.[1] Although Plaintiffs assert a variety of claimed deficiencies in these experts' opinions under Rule 702 (as well as alleged Rule 26 non-compliance by Drs. Robinson, Sanders, and Banner), every one of Plaintiffs' arguments reduces to the same theme. By Plaintiffs' account, Defendants' experts should be excluded because they determined that the body of (non-food) literature on which *Plaintiffs' experts* base their opinions is not a reliable source of scientific evidence for the general-causation question in this case—namely, whether consumption of Defendants' commercial baby food products can cause autism or ADHD. Plaintiffs' Motion attempts to turn the tables on the fatal flaw in their own causation experts' analyses—claiming that their experts' reliance on a body of scientific literature that *cannot* be reliably extrapolated to the question here is a methodological virtue, and Defendants' experts' sound rejection of those inapt studies is a methodological vice. By Plaintiffs' account, Rule 702 is little more than a counting exercise where an expert's methodology is judged by the number of studies she cites, not by the reliability of those studies or of her analysis. Nothing in Rule 702 supports this argument.

As explained in Defendants' Motion to Exclude Plaintiffs' Causation/Epidemiology Experts (Dkt. 614) ["Defendants' Causation Motion"], there is not a single study that examines whether there is an association between consumption of any food (let alone the healthy fruits, vegetables, and grains used to make baby foods) and autism or ADHD. And the non-food studies on which Plaintiffs' experts rely suffer from multiple defects that make them an unreliable fit for the general-causation question here. Those studies largely do not satisfy temporality (the bedrock criteria for finding causation), do not study the actual outcomes at issue in this litigation (diagnosed autism and ADHD), do not study populations with lead or arsenic exposure levels relevant to U.S. children, do

[1] Plaintiffs also moved to exclude the opinions of Drs. Carolyn Scrafford and Robert Gibbons (Dkt. 616). Defendants respond separately to that motion.

not find a rigorous statistical association, and more. Regardless of the number of studies they cite, none of Plaintiffs' experts applies a reliable methodology. Thus, if the Court agrees with Defendants' arguments for excluding Plaintiffs' experts on those grounds, it need not even consider Plaintiffs' Motion.

To the extent the Court does reach Plaintiffs' Motion, it fails on numerous levels.

First, as to Drs. Robinson, Sanders, and Banner, Plaintiffs claim that their failure to list by name in their expert reports all of the hundreds of inapt studies relied upon by Plaintiffs' experts constitutes a violation of Rule 26's disclosure obligations—and that this somehow merits wholesale exclusion of their opinions under Rule 37. That discovery motion is untimely and meritless.

Second, Plaintiffs attempt to recycle the arguments in their Rule 26 motion as a Rule 702 motion against Dr. Robinson, Dr. Sanders, Dr. Banner, and Dr. State—highly credentialed scientists who have collectively spent decades researching issues related to autism, ADHD, and heavy-metal exposure. Plaintiffs take issue with the fact that each of these experts concluded that the studies on which Plaintiffs' experts base their opinions do not provide reliable evidence of an association between consumption of baby food (or any other healthful food) and autism or ADHD. But unlike Defendants' Causation Motion—which explained in detail why Plaintiffs' experts' reliance on that body of literature reflects an unreliable methodology under Rule 702—Plaintiffs do not even attempt to identify any genuine methodological flaw in the defense experts' rejection of those studies. Plaintiffs' Motion flatly ignores the experts' clear and repeated descriptions of their methodologies, opting instead to repeat again and again that if these experts did not rely on the studies Plaintiffs' experts prefer, their opinions *must* be the result of impermissible cherry-picking or an otherwise unreliable method. Those arguments are contradicted by the facts and unsupported by the law.

Third, Plaintiffs criticize the opinions of Dr. Sanders, Dr. State, and Dr. Fombonne—three of the world's leading experts on autism—regarding the predominant role of genetics in the etiology of autism and ADHD. Tellingly, Plaintiffs do not dispute the uncontroverted science underlying these experts' opinions. Instead, Plaintiffs seek to exclude opinions that none of these experts have offered. For obvious reasons, those strawman arguments should be rejected.

Finally, Plaintiffs claim that the opinions of Dr. Kelleher (an expert in nutrition science), Dr. Tobias (a nutritional epidemiologist), and Dr. Filippelli (an expert in environmental exposures to heavy metals) are irrelevant to these Rule 702 proceedings. Plaintiffs are, once again, incorrect. Dr. Kelleher's opinions about the bioaccessibility and bioavailability of heavy metals when consumed in food, and Dr. Tobias's opinions about the impact of consuming foods with trace levels of lead or arsenic at the population level, shed light on why Plaintiffs' experts cannot reliably extrapolate studies about exposures to heavy metals through non-food sources to reach conclusions about whether baby food can cause autism or ADHD. Dr. Filippelli's opinion that the primary sources of heavy metal exposure in U.S. children are from environmental sources like soil, dust, and water (and that food is *not* a major exposure source) underscores a basic analytical gap in Plaintiffs' experts' causation opinions on baby food. In short, each of these experts provides context that helps to illustrate the fatal flaws in Plaintiffs' general causation theory. Such testimony is plainly relevant to the general causation question here.

Plaintiffs' Motion should be denied.

BACKGROUND

The defense experts who are the subject of Plaintiffs' Motion include world-renowned leaders in the study of autism, ADHD, toxicology, nutritional biochemistry, infant nutrition, and environmental exposure to heavy metals, among other subjects. Each expert reached their opinions after carefully considering the relevant scientific literature, reviewing the reports of Plaintiffs' experts pertinent to their area(s) of expertise, and drawing on their own substantial training, research, and experience outside of litigation. Although their areas of expertise differ, Defendants' experts agree that Plaintiffs' experts' analyses and opinions are riddled with methodological flaws and depend on a body of scientific literature that does not "fit" the general causation question and cannot reliably be used to determine whether commercial baby food—or any food—can cause autism or ADHD.

A. Elise Robinson, ScD, MPH

Dr. Robinson is Associate Professor in the Department of Psychiatry at Harvard Medical

School and the Center for Genomic Medicine at Massachusetts General Hospital (MGH), and an affiliated faculty member in the Department of Epidemiology at Harvard's T.H. Chan School of Public Health. Mot. Ex. 12, at 1 (Robinson Rep.).[2] Since completing her postdoctoral training, Dr. Robinson has published numerous peer-reviewed articles on the epidemiology and genetic architecture of autism and has been awarded numerous prizes for her research. *Id.* at 3. Dr. Robinson also leads a research group at MGH and the Broad Institute of MIT and Harvard that focuses on neurodevelopmental diagnoses—including autism and ADHD—with an emphasis on the intersection between neurodevelopmental genetics and epidemiology. Her research group is currently in the process of building a free, public, web-based suite of educational resources called MINERVA, which will provide empirically supported resources on autism genetics and clinical genetic testing to the autism community. *Id.* at 2.

B. Stephan Sanders, BMBS, Ph.D.

Dr. Sanders is Professor of Paediatric Neurogenetics at the Institute of Developmental and Regenerative Medicine in the Department of Paediatrics at the University of Oxford, England; an Adjunct Associate Professor in the Department of Psychiatry at the University of California, San Francisco (UCSF); and an affiliate of the New York Genome Center. His research focuses on the identification of risk factors for autism and other neurodevelopmental disorders, the neurobiology underlying neurodevelopmental disorders, and the development of therapeutic interventions for neurodevelopmental disorders. Mot. Ex. 5, at 1 (Sanders Rep.). Dr. Sanders has authored over 138 peer-reviewed articles, which have been cited over 43,000 times, as well as numerous reviews and several books and chapters. *Id.* at 2. Several of Dr. Sanders' publications have been recognized as notable contributions to the field of autism by organizations such as Autism Speaks, Spectrum, and the Interagency Autism Coordinating Committee. *Id.* He also serves on numerous international

[2] Documents cited as "Mot. Ex." refer to the exhibits filed at Dkt. 619, which accompany the Declaration of R. Brent Wisner in Support of Plaintiffs' Motion to Exclude Certain Testimony from Defendants' Expert Witnesses under FRCP 26 & 37 and FRE 702 (Dkt. 615-1). All other exhibit citations refer to the documents submitted with the accompanying Declaration of Neelum J. Wadhwani ("Wadhwani Decl.").

committees; for example, the International Society for Autism Research, the Scientific Advisory Board for the Autism Science Foundation, the World Congress Psychiatric Genetics Program Committee, and the Medical Genetics Committee for the SPARK initiative that aims to generate genetic data on 50,000 individuals with autism and their families. *Id.* at 2–3.

C. William Banner, Jr., M.D., Ph.D.

Dr. Banner is a physician with Board certifications in medical toxicology, pediatrics, and critical care pediatrics. Mot. Ex. 14, at 1 (Banner Rep.). He has published multiple articles regarding exposures to heavy metals. *Id.* As a practicing critical care pediatrician for more than three decades, he treated children with serious medical issues, including elevated levels of potential toxins. *Id.* Dr. Banner also held various professorships at medical schools in Arizona, Utah, and Oklahoma. Dr. Banner currently serves as the Medical Director of the Oklahoma Poison Control Center and previously served as President of the Board of Directors of the American Association of Poison Control Centers, President of the American Academy of Clinical Toxicology, and Chairman of the American Board of Medical Toxicology. *Id.*

D. Matthew State, M.D., Ph.D.

Dr. State is a board-certified child and adolescent psychiatrist and a physician-scientist with a doctorate in human genetics. Mot. Ex. 9, at 3 (State Rep.). He currently serves as a Distinguished Professor of Psychiatry and the Chair of Psychiatry and Behavioral Sciences at the University of California, San Francisco School of Medicine. *Id*. His laboratory has played a leading role in studying the genetics and biology of autism for two decades and has been recognized for multiple scientific breakthroughs in genetic discoveries as to autism. *Id*. at 4–5. Dr. State has received over 30 grants for autism research, including from the National Institutes of Health (NIH) and the Simons Foundation. *Id*. at 5. He also led the Simons Foundation Simplex Genomics Consortium from its inception and co-founded the NIH-funded Autism Sequencing Consortium, which continues to lead the field in identifying genes contributing to autism. *Id*. In 2018, Dr. State was among the top 1% of all authors cited in the world's scientific literature in the area of neuroscience and behavior. *Id*.

at 6. Dr. State has received multiple awards and was elected to the United States National Academy of Medicine in 2013 in recognition of his contributions to the field of autism research. *Id*.

E. Eric Fombonne, M.D.

Over his extensive career, Dr. Fombonne has researched, diagnosed, and treated a variety of childhood psychiatric disorders, including autism and ADHD. Mot. Ex. 7, at 3 (Fombonne Rep.). He has published over 380 scientific articles in peer-reviewed journals and over 50 book chapters, *id*. at 6, and his research has included designing and conducting numerous epidemiological studies on autism and ADHD, *see e.g. id*. at 3–5. Since 2012, Dr. Fombonne has been a Professor at the Oregon Health & Science University with cross-appointments in the Department of Pediatrics and the Department of Behavioral Neurosciences. *Id*. at 3. He also served as the Director of Autism Research at the Institute on Development and Disability and the Child Development and Rehabilitation Center, part of the Department of Pediatrics which provides services for children with developmental disabilities. *Id*. Among many other distinguished roles, Dr. Fombonne has been a reviewer or consultant to various agencies such as the CDC, the Institute of Medicine, the American Academy of Pediatrics, the Medical Research Council in the UK, the M.I.N.D. Institute, and NIH. *Id*. at 5–6.

F. Shannon Kelleher, Ph.D.

Dr. Shannon Kelleher is a nutrition scientist with expertise in nutritional biochemistry and infant nutrition. Mot. Ex. 1, at 4 (Kelleher Rep.). She earned a Ph.D. from the University of California Davis and is currently a Professor in the Department of Biomedical and Nutritional Sciences at the University of Massachusetts Lowell. *Id.* at 2–4. She has decades of direct research experience and has published over 105 peer-reviewed articles in the field of maternal and infant nutrition. *Id.* at 4. Dr. Kelleher has deep expertise in the molecular regulation of micronutrient (vitamin and mineral) transport and metabolism, infant nutrition, mammary gland biology, lactation, milk composition, and intestinal physiology and development.

G. Deirdre Tobias, ScD

Dr. Tobias is a nutritional epidemiologist and Assistant Professor of Medicine at the

Brigham and Women's Hospital and Harvard Medical School in Boston. She earned a Doctor of Science in both Epidemiology and Nutritional Epidemiology from the Harvard TH Chan School of Public Health (HSPH). Mot. Ex. 3, at 3 (Tobias Rep.). Dr. Tobias has published over 150 research articles in peer-reviewed medical journals and teaches methods for measuring, analyzing, and interpreting dietary exposures for population-based health outcomes research at HSPH. *Id.* She was selected to serve on the U.S. Dietary Guidelines Advisory Committee to analyze the scientific literature regarding what to eat and drink to meet nutrient needs, promote health, and prevent disease. *Id.*

H. Gabriel Filippelli, Ph.D.

Dr. Gabriel Filippelli is a Chancellor's Professor of Earth and Environmental Sciences at Indiana University. Mot. Ex. 16, at 2 (Filippelli Rep.). For more than two decades, Dr. Filippelli's research and publications have focused on the geochemistry of heavy metals in the environment and routes of environmental exposure to heavy metals (including through air, soil, dust, and water). *Id.* at 2–3. Dr. Filippelli has deep knowledge of and expertise in the predominant sources of environmental heavy-metal exposure in the small minority of U.S. children who are found to have elevated heavy-metal levels.

ARGUMENT

I. PLAINTIFFS' UNTIMELY DISCOVERY MOTION SHOULD BE DENIED.

Plaintiffs first seek to exclude all opinions offered by Drs. Robinson, Banner, and Sanders based on alleged discovery violations. Pl's. Mot. to Exclude Certain Testimony from Defendants' Expert Witnesses (Dkt. 615) ["Mot."] at 8–12. Specifically, Plaintiffs move to exclude these experts under Rule 26(a)(2)(B)(ii), claiming that they failed to disclose the "facts or data" they considered to form their opinions and that these alleged failures justify excluding the experts' testimony in its entirety under Rule 37. *Id.* at 2, 9. Plaintiffs' motion is untimely, meritless, and should be denied.[3]

[3] Defendants also refer the Court to the discussion regarding Plaintiffs' untimely Rule 26 motions in Section III of Defendants' Opposition to Plaintiffs' Motion to Exclude Dr. Carolyn Scrafford and Dr. Robert Gibbons, which is incorporated by reference herein.

A. Plaintiffs' Discovery Motion Should Be Denied as Untimely.

Because the Court set a discovery deadline of August 29, 2025, Plaintiffs were required to file any "discovery-related" motion by September 5, 2025. *See* Pretrial Order No. 15 (Mar. 27, 2025), at 3 (Dkt. 440); N.D. Cal. L.R. 37-3 ("[N]o discovery-related motions may be filed more than 7 days after the discovery cut-off."). They never did. Plaintiffs' Rule 26 and 37 arguments—raised in the context of the Court's scheduled Rule 702 proceedings—therefore come too late. *See Vinyards v. UPL, NA. Inc*., 2024 WL 4262393, at *8–9 (E.D. Cal. Sept. 19, 2024) (denying a motion to exclude expert for Rule 26 non-compliance because the moving party "made no showing of having raised this discovery dispute with the assigned magistrate judge before filing this attack as to the quality of the expert discovery").

Drs. Sanders, Robinson, and Banner produced their expert reports on June 20, 2025, and were deposed on August 8, 15, and 20, respectively—well before the August 29, 2025 expert discovery cutoff. During their depositions, Plaintiffs' counsel spent substantial time questioning each expert about the bases for their opinions, including the materials they considered. *See, e.g.*, Mot. Ex. 6, at 22:13–26:12, 91:25–95:8 (Sanders Dep.); Mot. Ex. 13, at 38:14–44:18, 49:25–55:19, 57:4–18, 64:17–66:5 (Robinson Dep.); Mot. Ex. 15, at 52:21–54:17; 78:11–80:25; 119:3–121:25; 123:14–125:17 (Banner Dep.). Plaintiffs did not claim—either before or after deposing these experts—that they were unable to conduct effective depositions as a result of the experts' materials considered lists. Plaintiffs never raised or sought to confer with Defendants about the supposed deficiencies identified in their Motion. They did not request that these three experts supplement their lists of materials considered. They did not seek additional deposition time—and in fact, did not even use close to the full seven hours allotted to them for each deposition. Nor did Plaintiffs move to compel these experts to produce a supplemental materials considered list, move to strike Defendants' expert disclosures, or otherwise file any kind of discovery motion *at all* within the allotted time frame. Wadhwani Decl. ¶¶ 5–8.

Instead, Plaintiffs waited until September 26, 2025—more than a *month* after deposing these experts and *three weeks* after the deadline for discovery motions—to file their present Motion

"under Rule 37" claiming alleged violations of Rule 26. Mot. at 9. This Motion was the first time Defendants heard of this issue and so reached out to Plaintiffs to meet and confer. But Plaintiffs claimed any conferral would be futile because it was somehow "too late," notwithstanding *Plaintiffs'* failure to timely raise these disputes. Wadhwani Decl. ¶ 9; Ex. 1, 10/8/25 Email.

Plaintiffs make no effort to justify their delay in raising this garden-variety discovery issue; they do not even attempt to explain why their Rule 26 motion does not run afoul of the seven-day time limit under Civil Local Rule 37-3. Plaintiffs have thus waived their right to raise this discovery matter, and the Court should deny Plaintiffs' motion for this reason alone.

B. Plaintiffs' Rule 26 Motion Should Be Denied on the Merits.

Even if the Court allows Plaintiffs' untimely discovery motion to proceed, their arguments fail on the merits. Plaintiffs' motion rests on misrepresentations of the experts' testimony and a misguided understanding of Rule 26's requirements.

Under Rule 26, an expert witness must disclose, among other things, "(i) a complete statement of all opinions the witness will express and the basis and reasons for them," and "(ii) the facts or data considered by the witness in forming them." Fed. R. Civ. P. 26(a)(2)(B). Drs. Robinson, Sanders, and Banner did exactly that. Each of these experts disclosed their "materials considered lists" with their expert reports on June 20, 2025 and supplemented those lists in advance of their depositions. Those lists cited, collectively, hundreds of scientific articles and other authorities that these experts considered in forming their opinions. *See* Mot. Ex. 5, at Ex. B (Sanders List of Materials Considered); Mot. Ex. 12, at Ex. B (Robinson List of Materials Considered); Mot. Ex. 14, at Ex. C (Banner List of Materials Considered).

To be sure, those lists did not include every one of the hundreds of articles identified by Plaintiffs' experts in their materials considered lists. But Rule 26 does not require experts for both sides to have identical reference lists. Moreover, Drs. Robinson, Sanders, and Banner each reviewed the Plaintiffs' expert reports relevant to their opinions—as reflected within their reports, materials considered lists, and supplements—and thus necessarily considered the studies described and relied upon by those Plaintiffs' experts in forming their opinions and responding to those experts. And as

Drs. Robinson, Sanders, and Banner each explained, having read those reports, they did not need to review or list many of the studies cited by Plaintiffs' experts because, on their face, those studies were either (1) redundant of other studies listed, (2) outside the scope of their opinions, or (3) most critically, not a reliable source of data on the actual general-causation question presented here: whether consumption of Defendants' baby food products is capable of causing autism or ADHD.

Plaintiffs' real quarrel with these experts appears to have less to do with their compliance with Rule 26 than with Plaintiffs' repeated insistence that the "hundreds" of studies Plaintiffs' experts cited—***none*** of which relate to heavy metal exposures through baby food, and almost all of which cannot reliably be applied to the general causation question for reasons Defendants' experts described in detail—are the "right" body of scientific literature on which to rely. *See, e.g.*, Mot. at 2 (claiming that Drs. Robinson's, Sanders', and Banner's "reports cite a fraction of the *relevant literature*"); *id*. at 9 (comparing Dr. Robinson's list of "160 references" to Dr. Ritz's "590 references"). But the fact that Defendants' experts did not (for very good reasons) rely on the studies Plaintiffs' experts prefer does not mean that their disclosures were deficient under Rule 26. Plaintiffs' argument therefore fails on the merits.

1. Dr. Robinson's Disclosures Complied with Rule 26.

Dr. Robinson's expert report was accompanied by a materials considered list containing "approximately *160 references* that she located using PubMed, within references of the literature, and from Plaintiffs' expert reports." Mot. at 9 (emphasis added). Plaintiffs nonetheless seek to exclude Dr. Robinson's opinions primarily because her materials considered list was not as long as Dr. Ritz's. *Id.* at 14 ("Dr. Robinson cited 157 publications in her materials considered list, which is less than 1/3 of the publications Plaintiffs' epidemiologist, Dr. Beate Ritz (590 references), considered on the same topics."). That argument fails on multiple levels.

The purpose of Rule 26's disclosure requirements is to ensure that parties against whom expert testimony is offered are not subjected to unfair prejudice or surprise. *See, e.g.*, *Pac. Steel Grp. v. Com. Metals Co.*, 2024 WL 4504534, at *1 (N.D. Cal. Oct. 16, 2024). There is no risk of surprise or prejudice here. Dr. Robinson's expert report discussed numerous studies related to

heavy-metal exposure and autism/ADHD and clearly defined the parameters of the literature she considered capable of reliably addressing the general causation inquiry (and why). *See, e.g.*, Mot. Ex. 12, at 6 (Robinson Rep). Her report also included a lengthy materials considered list identifying the specific sources she considered—including, among many other things, the expert reports of multiple Plaintiffs' experts (including Dr. Ritz). And Dr. Robinson described in detail her opinions and the bases for them. *See, e.g.*, *id.*

While Plaintiffs now claim that Dr. Robinson "ignored" hundreds of studies cited by Plaintiffs' experts that were "clearly relevant," her report and deposition testimony confirms the opposite: in addition to conducting her own independent literature review, Dr. Robinson carefully studied the materials considered lists furnished by Dr. Ritz and other Plaintiffs' causation experts and applied her disclosed methodology to determine whether the studies on those lists were informative of general causation (either by reviewing the titles and abstracts of those studies or reviewing the studies in their entirety). *See, e.g.*, Mot. Ex. 13, at 39:9–40:13; 41:8–42:14; 55:5–19 (Robinson Dep.). Plaintiffs' claim that they have "no way of knowing" what materials Dr. Robinson did and did not rely on, or whether Dr. Robinson applied a reliable methodology to her review of the scientific literature, is therefore simply wrong. Dr. Robinson made the criteria for her literature review clear in her expert report; disclosed materials accordingly in her materials considered list; and provided ample additional detail on that process at deposition. The fact that Plaintiffs may not like the answers Dr. Robinson provided is not a violation of Rule 26.

2. Dr. Sanders' Disclosures Complied with Rule 26.

Plaintiffs' Motion does not even pretend that Dr. Sanders relies on specific "facts or data" not disclosed on his materials considered list. Rather, their attack rests entirely on Dr. Sanders' unsurprising testimony that his opinions are broadly shaped by his general experience and work in the field of autism research, as well as his similarly unsurprising statements that he does not maintain (and so could not possibly cite) a record of every paper he has ever reviewed that might in some sense relate to how he views the issues in this case. Mot. Ex. 6, at 92:15–93:4 (Sanders Dep.) ("[My] opinions are shaped by my expertise in the field and so in truly understanding a field, it involves

taking a broad view of a lot of the work that is there and that is reflected in my opinions, but I'm not able to give a complete list of every single paper."); *id.* at 95:6–8 (testifying that he does not keep a list of every single paper he has read over the course of his career).

In other words, Plaintiffs' Rule 26 motion seeks to exclude Dr. Sanders for doing what experts routinely do: he disclosed the specific materials he considered in preparing his report, as required by Rule 26, and noted that he was also relying on his vast expertise and research in the field of autism over the course of many years. Plaintiffs provide no support for their apparent assertion that Rule 26 forbids this approach.

3. Dr. Banner's Disclosures Complied with Rule 26.

Plaintiffs criticize Dr. Banner for not listing a study that Plaintiffs claim addresses "arsenic exposure and neurodevelopmental toxicity." Mot. at 12 (citing Banner Dep. at 75:25–76:8). But when shown this study (Tsuji, et al. 2015) at his deposition, Dr. Banner confirmed that he did not need to "consider" it in forming his opinions because it involved children facing "a unique situation" in Bangladesh involving a "massive exposure" to arsenic in drinking water. *See* Mot. Ex. 15, at 75:25–77:7 (Banner Dep.). In other words, this study had *nothing* to do with exposures to the levels of heavy metals in food, let alone Defendants' commercial baby food products. Dr. Banner also explained that he did not consider certain studies that, for example, "didn't have anything to do with autism," *id.* at 120:19-121:3, or that otherwise pertained to "areas that I was not going to offer an opinion on," *id.* at 52:21–53:8. In any event, it cannot be the case that an expert violates Rule 26 by excluding from his materials considered list studies that he did not, in fact, consider.

* * *

At their core, Plaintiffs' arguments improperly suggest that Rule 26(a)(2)(B)(ii) is a numbers game, requiring Defendants' experts to consider—and therefore disclose with their reports—the same studies (or the same number of studies) cited by Plaintiffs' experts, including those that cannot reliably answer the general causation question in this case. Rule 26 imposes no such obligation.

II. DEFENDANTS' EXPERTS' OPINIONS ARE ADMISSIBLE UNDER RULE 702.

A. Dr. Robinson Applied a Reliable Methodology in Determining Which Scientific Literature Could Be Reliably Applied in Assessing General Causation.

Plaintiffs' arguments for excluding Dr. Robinson's testimony under Rule 702 are virtually identical to their arguments under Rules 26 and 37—and they fail for the same reasons. Contrary to Plaintiffs' assertions, Dr. Robinson did not "disregard" relevant studies or fail to disclose her methodology for determining which body of literature could reliably address the general-causation inquiry. Mot. at 13. And she certainly did not do so "without explanation." *Id.* Dr. Robinson explained in detail—both in her expert report and at deposition—the precise methodology she applied when determining what studies could reliably inform general causation.

In her expert report, Dr. Robinson explained that, based on her analysis, "the broader literature around lead and autism, arsenic and autism, and lead and ADHD" is not "informative to questions about *commercial baby food*"—including because "the great majority of th[e] studies" in that wider body of literature "do not address relevant doses, exposure contexts, or developmental time periods," and because many of those studies are "characterized by small studies, publication bias … , and a failure to control for confounders." Mot. Ex. 12, at 6 (Robinson Rep.) (emphasis added). She then catalogued the reasons that many of the specific studies and meta-analyses relied on by Plaintiffs' experts cannot be reliably extrapolated to the actual scientific question here. *E.g.*, *id.* at 23, 27–33. Dr. Robinson's report thus left no doubt as to the criteria she applied when assessing whether individual studies and meta-analyses could reliably inform her opinions.

When questioned at deposition about individual studies that she allegedly "ignored," Dr. Robinson reiterated the same methodological principles. For example, when shown a "semi-systematic" review authored by one of Plaintiffs' experts, which Plaintiffs cite in their Motion, Mot. at 10, Dr. Robinson explained that because she conducted her own ***systematic*** review of the literature, it would not make sense for her to "lean on a semi-systematic review of the same topic." Mot. Ex. 13, at 53:8–11 (Robinson Dep.) She further explained that, in any event, a "semi-systematic review is not … an epidemiologically sound approach to understanding the relationship

between two things." *Id.* at 54:1–4.

When shown the Mohamed (2015) study, which Plaintiffs claim "directly contradicts [Dr. Robinson's] opinion," Mot. at 11, Dr. Robinson promptly explained why studies conducted on non-U.S. populations (like the Mohamed study) are frequently "unable to speak to the U.S. context, and very specifically, the low levels of lead and arsenic in common foods in the United States," Mot. Ex. 13, at 62:6–15 (Robinson Dep.)—an observation that she had also made in her expert report, Mot. Ex. 12, at 32 (Robinson Rep.).

Likewise, when shown the Filon (2020) study—which assessed heavy metal exposure in *only 30 cases and 30 controls*—Dr. Robinson reiterated the points made in her expert report about the challenges of relying on studies with small sample sizes, and why such studies are often plagued by confounders that make it difficult, if not impossible, to reliably draw conclusions about causation. Mot. Ex. 13, at 58:10–25 (Robinson Dep.).

Finally, as to the FDA's publication on reference lead levels—which Plaintiffs assert "discusses the FDA's official position regarding the neurological effects of lead, as found in baby food, on infants," Mot. at 10—Dr. Robinson correctly pointed out that the FDA's "position" in that publication refers only to a "potential and a need to evaluate it," and not to a known association. Mot. Ex. 13, at 46:18–49:2 (Robinson Dep.) Because the FDA publication acknowledges that the association between dietary lead exposure and neurodevelopmental effects "is unknown," Dr. Robinson did not "believe this belongs in [her] review." *Id.* at 51:4–6.

Dr. Robinson's explanations leave no doubt that her methodology for identifying "relevant" scientific studies bears no resemblance to the kind of cherry-picking courts take issue with under Rule 702. Instead, she applied sound epidemiological principles—regarding dose, exposure routes, exposure source, temporality, publication bias, sample size, statistical significance, and more, *see, e.g.*, Mot. Ex. 12, at 6 (Robinson Rep.)—to the full body of scientific literature that she identified both through her own review and her review of Plaintiffs' expert reports and materials considered lists. Based on that methodology, Dr. Robinson concluded that "there is no reliable body of scientific literature supporting the conclusion that consumption of common foods, or commercial

baby food, is causally associated with autism or ADHD through exposure to lead or arsenic." *Id.* at 23. Plaintiffs offer no support for their apparent assertion that Dr. Robinson's repeated and unambiguous descriptions of her methodology were a façade designed to mask the fact that she rejected studies simply because they "contradicted her opinions." Mot. at 11. Once again, the fact that Plaintiffs do not like the conclusions Dr. Robinson reached does not render her methodology for reaching those conclusions unreliable or otherwise inadmissible under Rule 702.

B. Dr. Sanders' Opinions Are Grounded in Sound Science, Not Speculation.

Plaintiffs challenge Dr. Sanders' opinions under Rule 702 on two grounds: First, they claim that Dr. Sanders' opinion that there is no reliable evidence showing that exposure to heavy metals in Defendants' baby foods can cause autism is impermissible speculation because Dr. Sanders did not investigate the specific heavy metals levels in Defendants' baby foods. Mot. at 16. Second, they claim that Dr. Sanders' opinions tied to "the literature on the relationship between postnatal metal exposure and ASD" do not satisfy Rule 702 because he did not perform a Bradford Hill analysis. *Id.* Both arguments should be rejected.

Plaintiffs' claim that Dr. Sanders failed to assess the heavy metal levels in Defendants' baby food products is a strawman. Dr. Sanders does not need to know the levels of arsenic and lead in Defendants' products for his opinions to be reliable because his ultimate opinion—supported by reliable scientific methodology—is that there is no reliable scientific evidence that *any* dose of heavy metals consumed in baby food causes autism. As Dr. Sanders explains in his report, his opinions are based, *inter alia*, on: (a) the fact that "there are no published, peer-reviewed studies examining whether there is a relationship between the consumption of commercial baby foods and ASD risk;" (b) the general scientific consensus that there are only "a few non-genetic factors with consistent findings of a correlation to ASD," specifically, increased parental age, prematurity, and *in utero* exposure to sodium valproate (antiepileptic medication); and (c) there is no replicated, consistent finding in the peer-reviewed literature demonstrating an association – much less causation – between any postnatal environmental exposures, at any levels, and autism. Mot. Ex. 5, at 16–17 (Sanders Rep.). In the absence of any scientific data anywhere showing a link between eating

healthy food and autism, Dr. Sanders' opinions simply do not turn on a specific level of any heavy metal in a specific food.

The absence of any reliable evidence of an association also means that Dr. Sanders did not need to perform a Bradford Hill analysis of literature examining postnatal metal exposures and autism. As Dr. Sanders explained: "The step before doing a Bradford Hill analysis is to demonstrate association between a factor and the phenotype, in this case autism. That bar has not been reached and so therefore I did not feel the need to do a Bradford Hill analysis." Mot. Ex. 6, at 22:8–12 (Sanders Dep.). Dr. Sanders is correct as a matter of science and the law. Courts regularly emphasize that a reliable association must be established as a prerequisite to a Bradford-Hill analysis. *See, e.g.*, *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 265 (S.D.N.Y. 2018) ("[A]bsent such an association, there is no basis to apply the Bradford Hill criteria."), *aff'd sub nom*. *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 982 F.3d 113 (2d Cir. 2020).

C. Dr. Banner Applied Reliable, Consistent Standards to His Analysis of The Scientific Literature.

Plaintiffs ask the Court to exclude the opinions of Dr. Banner, contending that they derive from an unreliable methodology. Mot. at 16–19. Plaintiffs' arguments rest on cherry-picked deposition excerpts that fail to accurately characterize Dr. Banner's charge and the bases for his opinions. Plaintiffs' motion should be denied.

As explained in his report, Dr. Banner reviewed the reports of Plaintiffs' experts Drs. Hu, Guilarte, and Aschner, and concluded those experts' opinions were not "based on sound scientific or medical analysis." Mot. Ex. 14, at 2 (Banner Rep.); *see also id.* at 8–11 (discussing the methodological flaws of Plaintiffs' experts). Among other glaring issues, Dr. Banner observed that none of the studies cited by Plaintiffs' experts assess "the consumption of baby food as the source of exposure" to lead or arsenic (a fact Plaintiffs do not dispute). *Id.* at 2–3; *see also* Mot. Ex. 15, at 148:7–23 (Banner Dep.).

Even setting aside that fundamental problem, Dr. Banner discussed multiple other

methodological flaws in Plaintiffs' experts' analyses, including, for example, their failure to adequately account for "reverse causation," a common complicating factor in epidemiological studies. Mot. Ex. 14, at 10–11 (Banner Rep.). As he explained in his deposition, Dr. Banner scrutinized the flaws in Plaintiffs' experts' reports by examining the studies they focused on, and conducting additional literature searches, as necessary, to identify sources cited within those articles. *See* Mot. Ex. 15, at 33:6–34:10 (Banner Dep.). Nowhere in their motion do Plaintiffs explain why this approach required Dr. Banner to "consider" *every single* study cited by Drs. Aschner and Guilarte, which Plaintiffs appear to suggest is the proper measure of the reliability of his methodology. *See* Mot. at 18. That argument finds no footing in Rule 702 or *Daubert.*

Plaintiffs acknowledge that Dr. Banner's opinions "consist primarily of criticisms of Plaintiffs' experts." *Id.* at 4. But they then fault him for not undertaking a "Bradford Hill" analysis or a systematic review of the same hundreds of articles (again, none of which evaluate consumption of baby food) listed by Plaintiffs' experts.[4] Plaintiffs cite no Rule 702 authority mandating such methodologies, particularly given the limited scope of Dr. Banner's opinions. Rather, "an expert can critique the methodology of another expert without" conducting his own independent analysis or affirmatively disproving the matter himself. *Faryniarz v. Nike, Inc.*, 2002 WL 1968351, at *2 (S.D.N.Y. Aug. 23, 2002). That is precisely what Dr. Banner did here, drawing on his decades of research and clinical practice in pediatrics and toxicology to opine that a toxicological "causal assessment" requires "proper qualitative scrutiny" beyond the mere "counting studies of 'association,'" which Plaintiffs' experts failed to undertake. Mot. Ex. 14, at 9 (Banner Rep.). Plaintiffs' arguments ignore that it is ***their*** burden to show that their experts adopted a reliable methodology to establish general causation. Instead, they improperly attempt to shift the burden of disproving their causation theory to Dr. Banner.

[4] Dr. Banner testified that he identified ***no*** reliable studies finding an association between consumption of commercial baby food and ASD or ADHD. Mot. Ex. 15, at 79:4–16; 148:7–23 (Banner Dep.). Because a "statistically significant association" is a prerequisite to applying the Bradford Hill criteria, *see* Defs.' Causation Brief, at 4–5, Plaintiffs' suggestion that Dr. Banner should have undertaken that analysis lacks merit.

Plaintiffs' Motion fixates on a single comment by Dr. Banner, in which he labeled his efforts to identify reliable literature the "Banner methodology." Mot. at 17. This was plainly an attempt at humor, and Plaintiffs ignore the fact that Dr. Banner then dismissed this label as "silly." Mot. Ex. 15, at 134:10–13 (Banner Dep.). In reality, Dr. Banner clearly laid out his methodology in his report and at deposition: he reviewed Plaintiffs' expert reports, identified certain epidemiological studies that they appeared to view as important, and then identified flaws in their discussion of those studies, including their failure to recognize critical limitations in those studies' designs and conclusions. Mot. Ex. 14, at 9–11 (Banner Rep.); Mot. Ex. 15, at 35:1–16 (Banner Dep.) (explaining that he reviewed "what plaintiff[s'] reports" considered to be "important); *id.* at 154:11–24 (explaining that he "first looked at the plaintiffs'" references and conducted additional searches where needed).

Finally, Plaintiffs contend that Dr. Banner "offers no reliable basis for his opinion that certain nutrients in commercial baby food offset the effects of lead and arsenic." Mot. at 19. But during his deposition, Dr. Banner pointed to several references supporting that opinion. Mot. Ex. 15, at 130:2–134:14 (Banner Dep.). Plaintiffs criticize Dr. Banner for failing to identify "more studies" on this topic, but they fail to acknowledge that his opinions can also properly be informed by his decades of research and clinical practice treating children exposed to toxins. *See* Fed. R. Evid. 702(a).

D. Dr. State's Opinions on Lead and Arsenic Are Based on a Reliable Methodology that Applied Sound Scientific Principles to the Available Literature.

Consistent with the scientific consensus, his analysis of the scientific literature, and his extensive research and experience with autism, Dr. State opines that there is no reliable evidence establishing that early childhood exposure to lead or arsenic can cause autism. *E.g.*, Mot. Ex. 9, at 7–11 (State Rep.). Specifically, Dr. State opines, *inter alia*, that (1) no studies analyze whether baby food is associated with autism; (2) there are no early childhood exposures of any kind that have been shown to cause autism; (3) there is no reliable scientific evidence that exposure to lead or arsenic before or after birth causes or contributes to autism; and (4) only a handful of presumably non-genetic risk factors for autism have been established, all of which relate to prenatal characteristics

or *in utero* exposures. *Id.* at 7–10. Plaintiffs' Motion first recycles some of their criticisms directed at Drs. Robinson and Sanders to attack these opinions. Namely, Plaintiffs criticize Dr. State for not relying on the same inapt studies that Plaintiffs' experts use to support their causation opinions. Separately, Plaintiffs also claim that he applied an unreliable methodology to reach his opinions regarding lead and arsenic exposures and autism. Tellingly, Plaintiffs offer no case law to justify excluding an opinion that is in line with the scientific consensus and endorsed by Plaintiffs' own expert. Plaintiffs' arguments should be rejected.

1. Dr. State Did Not Disregard Studies.

Plaintiffs claim that Dr. State "disregard[ed] … hundreds of studies without any critical evaluation." Mot. at 19. Dr. State did not "disregard" anything. Instead, he critically reviewed the studies identified through his own literature review and his review of Plaintiffs' expert reports to determine if they were capable of reliably answering the causation question at hand. *E.g.*, Mot. Ex. 9, at 7 (State Rep.); Mot. Ex. 11, at 124:10–125:15 (State Dep.). Dr. State spent approximately 220 to 280 hours reviewing more than 500 scientific articles and texts—including hundreds of studies relied on by Plaintiffs' experts. *See* Mot. Ex. 9, App'x B (State List of Materials Considered); Mot. Ex. 11, at 36:9–15, 39:6–40:6 (State Dep.). As Dr. State testified: "I definitely used [the studies cited by Plaintiffs' experts]. ***I looked at everything***. And, again, I think that the issue here is that I didn't ignore studies, you know. I looked at them. And, again, like anytime you're trying to answer a question in the literature, there's the threshold question: Is this study designed in a way that can give me a reliable answer?" Mot. Ex. 11, at 134:8–135:2 (State Dep.) (emphasis added).

As described more fully below, Dr. State explained in detail why most of the studies he reviewed are incapable of providing reliable evidence of a causal relationship between early-life heavy metal exposure and diagnosed autism or ADHD—both because there are ***no*** studies analyzing whether consuming baby food is associated with autism (an incurable gap in Plaintiffs' theory) and because, for many reasons, the studies on which Plaintiffs' experts rely are not a proper fit for the general-causation question here.

2. Plaintiffs' Expert Agrees Dr. State's Methodology Is Reliable.

Dr. State explained that the vast majority of the studies on which Plaintiffs' experts rely (1) fail to establish temporality; (2) fail to use the proper endpoint—diagnosed autism—and instead use general symptoms or behaviors that cannot be used a reliable proxy for actual diagnoses; (3) fail to use a rigorous statistical analysis to identify a reliable association; and/or (4) do not address the role of confounders. Plaintiffs' Motion argues, somewhat bizarrely, that Dr. State's opinions should be excluded because he relied on these established scientific principles when assessing whether the available scientific literature demonstrates a reliable association between early life heavy metal exposure and autism. *Id.* at 20–22. That argument makes no sense. Dr. State's consideration of these bedrock scientific criteria *reinforces* rather than refutes the reliability of his methodology.

Temporality. While it is true that temporality is one of the Bradford Hill criteria, Mot. at 21, consideration of temporality is not limited to Bradford Hill. Rather, evaluating temporality is a fundamental requirement in *any* causation analysis. *See* Reference Manual on Scientific Evidence (3d ed. 2011) ["Ref Manual"] at 601 ("A temporal, or chronological, relationship must exist for causation to exist."); *see also Davis v. McKesson Corp.*, 2019 WL 3532179, at *32 (D. Ariz. Aug. 2, 2019) ("A cause must precede its effect."); *In re Mirena II*, 341 F. Supp. 3d at 242–43 (same). Indeed, Plaintiffs' expert, Dr. Tomas Guilarte, affirmed the importance of assessing temporality when conducting any kind of causal analysis. He agreed that "without exposure before the disease, causation cannot exist," and that "epidemiological studies that do not establish that exposure came before the disease cannot establish causation." Ex. 2, at 112:12–113:6 (Guilarte Dep.). And while Plaintiffs criticize Dr. State for determining that only 13 of the 117 lead studies he reviewed satisfied the temporality requirement, Mot. at 20–21, Dr. Guilarte also admitted that most of the epidemiological studies on heavy metals and autism or ADHD are cross-sectional and case-control studies that could not establish temporality, Ex. 2, at 111:18–112:2; 113:19–116:16 (Guilarte Dep.).

Endpoint. An actual diagnosis of autism is critical to ascertaining whether baby food can "cause" autism—as Plaintiffs' own expert admitted. Ex. 2, at 71:18–72:4 (Guilarte Dep.) ("Q. Doctor, to reach reliable opinions about causation of ASD, you need to look at *diagnosed* ASD,

correct, Doctor? A. Correct. Q. And the same is true for ADHD, correct? A. Correct.") (emphasis added). Courts considering claims related to autism and ADHD causation have also recognized this. *See In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, 707 F. Supp. 3d 309, 340–42 (S.D.N.Y. 2023) (excluding expert who based their opinions on studies that failed to measure autism and ADHD as the endpoint without explaining why such studies could reliably inform general causation). That is because autism/ADHD "symptoms" or scores on behavioral scales are not the same thing as diagnosed autism/ADHD. As discussed by Dr. State, symptom "scales such as the widely cited social reciprocity scale (SRS) may be elevated due to symptoms unrelated to [autism] … and even when scores are in the 'clinical range,' most children exceeding this threshold will not have [autism] with or without ADHD." Mot. Ex. 9, at 31–32 (State Rep.). Indeed, Kim 2016, a study heavily relied upon by Plaintiffs' experts, makes this point clear: "clinical ASD and autistic behaviors evaluated using tools such as the ASSQ or SRS are not the same." Mot. Ex. 23, at 198 (Kim, et al. 2016). Dr. State's careful consideration of whether a scientific study examined the relevant endpoint illustrates the reliability of his method.

Statistical Rigor. Dr. State's reliance on the importance of statistical rigor, including abiding by established significance thresholds, is a hallmark of reliability—another point that Plaintiffs' expert Dr. Guilarte agreed with. Ex. 2, at 73:16–74:2 (Guilarte Dep.) ("Q. But based on my review of the studies – of your studies, your published work, when the results in your studies are not statistically significant, you conclude that there's no difference between groups or no association, correct? THE WITNESS: Correct Q. And that's just a generally accepted and reliable statistical methodology, correct? THE WITNESS: Correct."). Dr. State's requirement of statistical rigor also accords with long-standing case law. *See In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1177–78 (N.D. Cal. 2007) (excluding expert's opinion that Celebrex can cause heart attacks or stroke where expert relied on studies that did not show a statistically significant association between Celebrex use and heart attacks or strokes).

Confounders. Dr. State's emphasis on the need for studies to address confounders—like genetics, family history, socio-economic status, and nutritional deficiencies—to establish causation

is similarly sound and accepted science. As the Reference Manual explains, "[i]n assessing causation, researchers first look for alternative explanations for the association, such as bias or confounding factors." Ref. Manual at 598. Only after that "process is completed" should "researchers consider how guidelines for inferring causation from an association apply to the available evidence." *Id.*; *see also id.* at 572 ("Three general categories of phenomena can result in an association found in a study to be erroneous: chance, bias, and confounding. Before any inferences about causation are drawn from a study, the possibility of these phenomena must be examined."). Courts have likewise explained that "[a]lternative explanations, such as bias or confounding factors, should first be considered." *Coleman v. BP Expl. & Prod., Inc.*, 2022 WL 2314400, at *4 (E.D. La. June 28, 2022) (citation and quotation marks omitted), *reconsideration denied sub nom. Dawkins v. BP Expl. & Prod., Inc.*, No. CV 17-3533, 2022 WL 4355818 (E.D. La. Sept. 20, 2022). Plaintiffs' expert Dr. Guilarte similarly agreed that epidemiological studies of heavy metals and neurodevelopmental outcomes, including ASD, should control for confounders such as socioeconomic status, genetics, and reverse causality. Ex. 2, at 103:6–20; 158:1–9; 205:1–7, 208:10–20; 227:2–10 (Guilarte Dep.).

* * *

The methodology that Dr. State used is reliable, consistent with the requirements of Rule 702, and endorsed by Plaintiffs' own experts.[5] There is no basis to exclude those opinions under Rule 702.

[5] As for Plaintiffs' claim that studies assessing "biological plausibility" and "non-human data" make up for a lack of reliable human data (*see* Mot. at 21), both of their toxicology experts refute that assertion. *See* Ex. 2, at 77:4–12 (Guilarte Dep.) ("Q. An association that is observed in an animal study may or may not hold true in humans, correct? THE WITNESS: Yes. Q. Okay. The only way to find out whether it will hold true in humans is to look at human data, correct? THE WITNESS: Correct."); Ex. 6, at 12 (Aschner Rep.) ("There are many reasons why animal studies can be poor predictors of human outcomes, and why they fail to translate to human responses.").

E. Defendants' Experts Appropriately Considered the Established Heritability of Autism and ADHD in Evaluating General Causation.

Plaintiffs do not and cannot dispute that both autism and ADHD are highly heritable.[6] Indeed, Plaintiffs' own experts agree that autism is a "genetic condition," Ex. 3, at 162:21–163:12 (Reed Dep.), and they even admit that genetics alone can cause ASD and ADHD, Ex. 2, at 42:23–43:6 (Guilarte Dep.); Ex. 4, at 202:8–18 (Ritz *Landon R.* Dep.). At least one of Plaintiffs' experts admits that there is genetic influence in every case of autism. Ex. 5, at 84:5–13, 100:12–16 (Shapiro *Landon R.* Dep.). The role of genetics in autism and ADHD is therefore deeply relevant to *any* assessment of the causes of these disorders, including the general causation inquiry here.

Plaintiffs' Motion nonetheless attacks Drs. Sanders', Fombonne's, and State's opinions regarding the generally accepted fact that autism and ADHD are among the most highly heritable of all common medical conditions. But rather than identify any scientific or methodological flaw in these experts' heritability opinions that would justify exclusion, Plaintiffs challenge opinions these experts never offered. Plaintiffs' arguments are meritless.

Plaintiffs first contend that Drs. Sanders, State, and Fombonne should be forbidden from "rely[ing] on heritability to opine that genes cause all [autism] or ADHD." Mot. at 36. But Defendants' experts do not do this. To the contrary, all three experts agree "that the field generally accepts that there are environmental exposures *in utero*, or nongenetic factors" that may contribute to autism and ADHD. Mot. Ex. 11, at 70:17–20 (State Dep.); *see also id.* at 90:1–8 (explaining that "increased paternal and maternal age, prematurity, extreme prematurity … are the -- those three are the most widely accepted [non-genetic] risk factors" for autism); *id.* Mot. Ex. 7, at 28 (Fombonne Rep.) (discussing prenatal "environmental risk factors" and stating "most robust associations relate to maternal health problems occurring before or during pregnancy"); Mot. Ex. 6, at 121:5–7 (Sanders Dep.) ("We also need to account for the known non-genetic factors, so, for example, prematurity or parental age."). Drs. Sanders, State, and Fombonne also explained, however, that

[6] "Heritability" is "a measure of how much variation in a trait at the population level is due to genetic influence." *In re Acetaminophen*, 707 F. Supp. 3d at 320.

there is only reliable scientific evidence for a small number of non-genetic risk factors for autism—and that the list of recognized non-genetic risk factors does not include any post-natal environmental exposures, such as heavy metals. *E.g.*, Mot. Ex. 5, at 16 (Sanders Rep.); Mot. Ex. 9, at 52–53 (State Rep.); Mot. Ex. 7, at 7 (Fombonne Rep.). Plaintiffs are therefore attacking an opinion no expert is offering.

Plaintiffs then suggest that Defendants' experts misstate the meaning and role of heritability by equating heritability to the percentage of autism or ADHD cases caused by genetics vs. environmental factors. Mot. at 36. But in the only testimony Plaintiffs cite to support this argument, Dr. Sanders explicitly agreed that this is *not* what heritability means. *See id*. (quoting Sanders Dep. at 35:3–8 ("Q. Just because heritability of autism, as you reported in your report, is around 80%, that does not mean that a child with a gene associated with autism has an 80% chance of developing autism; true? A. You're correct that those two numbers are not comparable.")). Neither Dr. State nor Dr. Fombonne suggests otherwise.

Finally, Plaintiffs suggest that the Court should exclude these opinions because jurors might not understand heritability. Mot. at 37. But there is no reason to think that jurors are unable to grasp scientific terms when explained by a qualified expert. Jurors are regularly called upon to grapple with complex scientific principles, with the assistance of expert witnesses—indeed, the entire purpose of expert testimony is to help jurors understand relevant issues that might be outside their common understanding. *See* Fed. R. Evid. 702. Tellingly, Plaintiffs fail to cite a single case to support their claim that a reliable and widely accepted opinion—like the heritability of autism and ADHD—must be excluded because of the mere possibility that jurors might find that opinion hard to understand. Nor could they, as that argument has no support under Rule 702.

F. Dr. Kelleher's Opinions on the Impact of Healthy Foods Address a Key Causation Issue and are Based on Well-Established Scientific Principles.

Plaintiffs claim that Dr. Kelleher's opinions (i) "lack fit" and (ii) are speculative and unsupported by data. Mot. at 22. Both arguments should be rejected.

1. Dr. Kelleher's Opinions Fit the General Causation Question.

Dr. Kelleher's opinions concern a key general causation issue: why the route of exposure to heavy metals matters. Plaintiffs' causation experts concede that no epidemiological study finds an association between commercial baby food (or even food generally) and autism or ADHD. *See* Defs.' Causation Mot. at 8 (Dkt. 614). They instead rely on epidemiological studies that assess exposure to lead or arsenic from ***any*** source and through ***any*** route of exposure to support their opinions regarding consumption of Defendants' baby foods. *See id.* Plaintiffs' experts ignore entirely that food is a complex matrix comprised of nutrients and non-nutrient compounds (such as fiber and phytate) that, first, limit the body's extraction of lead or arsenic from the food during digestion and, then, significantly reduce or eliminate the absorption of any extracted lead or arsenic into the bloodstream. Dr. Kelleher's opinions highlight the unreliability of Plaintiffs' experts' methodology, exposing a critical analytical gap in Plaintiffs' general causation theory: if dietary lead and arsenic are not extracted from the small intestine and absorbed into the bloodstream (but rather are excreted in urine or stool), they can have ***no*** impact on the brain.

Dr. Kelleher's opinions "fit" the general causation inquiry because she examines the role of the food matrix in limiting the body's extraction of lead and arsenic (bioaccessibility) and absorption of these metals into the blood and brain (bioavailability). Although Plaintiffs' expert Dr. Jones purports to convert the levels of lead she calculated in hypothetical baby food menus to a blood lead level via the EPA's IEUBK model, she failed to consider the actual rates of infant absorption of heavy metals from baby food. Ex. 7, at 525:24–526:16 (Jones Dep. Vol. II) (testifying that she used the default absorption value for the gut in the IEUBK model). For the reasons stated in Defendants' Motion to Exclude Plaintiffs' Exposure Experts, that methodology is unreliable. Defs.' Exposure Mot. at 10–11 (Dkt. 612). By contrast, Dr. Kelleher addresses this question of dose: how much, if any, ingested lead or arsenic from baby foods is extracted from the intestine, absorbed into the bloodstream, and distributed to body tissues (biodistributed). *See, e.g.*, Mot. Ex. 2, at 10:20–11:12 (Kelleher Dep.) ("if lead is not bioavailable, it's not crossing the small intestine to get into the blood, and it's not going to be distributed, biodistributed to the brain"); *id.* at 41:2–17 (the food matrix is

"always going to have an effect, a very important effect, on reducing the bioaccessibility" of lead). Similarly, Dr. Jones agreed that the Ziegler study (1978) cited by Dr. Kelleher "indicat(es) that the rate of excretion (of lead) in the feces and the urine is greater than the rate of intake from the food" in infants and young children who consume low levels of lead in food. Ex. 7, at 534:24–537:20 (Jones Dep. Vol. II). Thus, Dr. Kelleher's opinions speak directly to the impact of nutrients in food, including Defendants' baby foods, on the absorption of lead and arsenic.

Plaintiffs next contend that Dr. Kelleher's opinions "lack fit" because she does not identify a specific level of exposure at which the "bioaccessibility, bioavailability or biodistribution of lead [is] no longer significantly affected by the nutrients in the food matrix." Mot. at 24. This argument, however, flips the burden of proof. It is ***Plaintiffs'*** burden to prove, through admissible expert testimony, that the levels of lead or arsenic in Defendants' baby food can cause autism or ADHD. Thus, Plaintiffs' experts are required (but fail) to establish that they reliably accounted for the impact of the food matrix on lead and arsenic uptake to reach their causation opinions. *Engilis v. Monsanto Co.*, 151 F.4th 1040, 1049 (9th Cir. 2025) (Rule 702 "always" requires the proponent to "establish the admissibility criteria of Rule 702 by a preponderance of the evidence.").

Plaintiffs also argue that Dr. Kelleher was unable to "explain the mitigating effects of nutrients on heavy metal absorption on a *population level*." Mot. at 24 (emphasis in original). To the contrary, Dr. Kelleher explained that "[i]t's a fundamental principle" that absorption is "always going to be affected by the nutrients and the non-nutritive factors that are in the diet" and noted that numerous studies have shown that "the presence of food reduces lead absorption." Mot. Ex. 2, at 38:23–39:24 (Kelleher Dep.). Plaintiffs' expert Dr. Beate Ritz also concedes that food can counteract the impact of heavy metals. Ex. 8, at 269:11–17 (Ritz *N.C.* Dep., Apr. 10, 2023) ("Q. Doctor, you have previously testified that, if mercury comes from certain types of fish that also contains omega-3 fatty acids, we discussed this earlier, that the adverse effect of mercury is counteracted most likely by the beneficial effects in fish eating; correct? A. That can happen, yes.").

Lastly, Plaintiffs argue that Dr. Kelleher's opinions are somehow inadmissible because she cannot specify the exact reduction in absorption for a given child. Mot. at 24. To start, that criticism

bears on *specific* causation, which is *not* the subject of Dr. Kelleher's opinions in this general causation proceeding. Setting that aside, Plaintiffs' criticism rests on testimony they take out of context. Dr. Kelleher actually testified that there is no single "database" that "outlines all of these different nutritional factors and their concentrations in specific food groups, let alone how they interact," to definitively calculate the impact of the nutrient and non-nutrient factors in food that could impact bioaccessibility and bioavailability of lead. Mot. Ex. 2, at 26:15–27:3 (Kelleher Dep.) But such a calculation would not change the fact that the general, well-established principles of bioaccessibility and bioavailability are clear at a population level, as Plaintiffs' expert, Dr. Ritz, acknowledged. Ex. 9, at 239:17–240:11 (Ritz. Dep.) (stating that these compounds can impact absorption "unless they are broken down by the microbiome or the acids in the – in the stomach").

2. Dr. Kelleher's Opinions Are Based on Established Science.

Finally, Plaintiffs argue that Dr. Kelleher's bioaccessibility opinions are speculative. This argument should be rejected. Plaintiffs selectively quote Dr. Kelleher's testimony to create the misimpression that her opinions on bioaccessibility and the infant gastrointestinal system are based on mere "assumptions." Mot. at 25. But at her deposition, Plaintiffs asked Dr. Kelleher to identify articles supporting her opinions on bioaccessibility. She readily offered a list—undercutting any suggestion by Plaintiffs that her opinions are mere "speculation."[7] Mot. at 25.

Plaintiffs also claim Dr. Kelleher's opinions are speculative because she extrapolates from some studies on nutrients such as calcium and iron. Mot. at 25. These studies were merely further explanation for Dr. Kelleher's opinion "that food has a very important effect on mitigating the absorption of lead." Mot. Ex. 2, at 51:6–52:3 (Kelleher Dep.); *see also* Mot. Ex. 1, at 31–32 (Kelleher Rep.). Importantly, Plaintiffs' own experts do not dispute this. Ex. 10, at 212:18–213:3

[7] *See* Mot. Ex. 2, at 120:5–125:3 (Kelleher Dep.) (referencing Bourlieu (2004), Davidsson (1994), Davidsson (1996), Demers-Mathieu (2018), Gibson (2007), Griggs (2021), Holland (2020), Intawongse (2008), Ismail-Beigi (1977), Jaiswal (2022), Kozu (2025), Kumar (2021), Kumari (2023), Liu (2024), Perera (2023), Piskin (2022), Rousseau (2018), Schweiggert-Weisz (2024), Sotelo (2010), Wang (2022), Zhuang (2024), Abrams (1997), Lonnerdal (2017), Lonnerdal (2005), Hambidge (2006)).

(Hu Dep.) ("Minerals, including iron and calcium, have been associated with lower lead concentration and may decrease lead absorption by competing for shared absorptive receptors in the intestinal mucosa."); Ex. 11, at 144:3–23 (Gardener Dep.) ("consumption of calcium and iron may act as antagonists for lead and cadmium").

Plaintiffs' argument that Dr. Kelleher's opinions are inconsistent with government reports is similarly without basis. Plaintiffs rely on ATSDR and FDA statements that children absorb a higher percentage of ingested lead than adults to criticize Dr. Kelleher's opinions that children are not absorbing substantial lead or arsenic from baby food. Mot. at 25–26. Dr. Kelleher agrees that infants can absorb more lead than adults *through non-food exposures*; her point is that the food matrix and nutrient content of baby foods specifically reduce both extraction and absorption of heavy metals. Mot. Ex. 2, at 51:5–52:3 (Kelleher Dep.) ("All of the factors that I've described in my report and that we've been talking about do need to be taken into consideration if you want an accurate understanding of how much lead a child is or is not absorbing."). The EPA itself has emphasized the point that food, and the nutrients in food, prevent lead absorption.[8]

Finally, Plaintiffs claim that Kordas (2024) and Desai (2021) undercut Dr. Kelleher's opinions. Mot. at 26. Once again, Plaintiffs' selectively (and misleadingly) characterize those studies to support their preferred outcome. Dr. Kelleher clearly explained her bases for relying on those studies. Mot. Ex. 1, at 44–45 (Kelleher Rep.). Plaintiffs offer no explanation for why Dr. Kelleher's reliance on those studies was scientifically unsound or the result of an unreliable methodology under Rule 702.

In short, Dr. Kelleher offers opinions directly relevant to the general causation inquiry. Those opinions are backed by reliable science that Plaintiffs' own experts cannot (and to a large degree do not) dispute. Plaintiffs' motion as to Dr. Kelleher should be denied.

[8] EPA, Lead Awareness Program (Nov. 2001), https://www.epa.gov/sites/default/files/documents/nutrition.pdf (consuming 4-6 meals per day, and consuming iron-rich, calcium-rich, and vitamin C-rich foods, can "reduce lead absorption").

G. Dr. Tobias's Opinions on the Neurodevelopmental Benefits of Baby Foods, and the Lack of Any Science to Connect Those Foods to Autism or ADHD, Are Relevant and Reliable.

Plaintiffs seek to exclude Dr. Tobias's opinions regarding (1) the importance of baby foods for infants and toddlers, including their beneficial effects on neurodevelopment, and (2) the consistency of Dr. Tobias's findings with the widely held scientific view that there are no accepted postnatal, non-genetic causes of autism. Both opinions are reliable and relevant to general causation.

1. Dr. Tobias's Nutrition-Based Opinions Are Relevant to General Causation.

Plaintiffs first take issue with Dr. Tobias's opinion that "[c]ommercial baby food products provide optimal nutrition and variety for the critical window from the introduction of complementary foods to 4 years[.]" Mot. at 27 (quoting Mot. Ex. 3, at 5 (Tobias Rep.)). Plaintiffs claim that these opinions are irrelevant because they do not answer the question as to "whether levels of heavy metal exposure from consumption of Defendants' baby food products are capable of harming neurodevelopment." *Id.* But Plaintiffs' causation theory hinges on the notion that consuming Defendants' baby foods can be harmful to developing brains. Dr. Tobias's opinions illustrate why baby foods and the nutrients they contain are beneficial, not harmful, to babies' neurodevelopment. Such testimony is plainly relevant.

Dr. Tobias opines that the available scientific literature shows that consuming nutrient-dense foods is associated with positive neurodevelopmental outcomes in children. Dr. Tobias cites a study that found that in infants 6-12 months of age, "baby foods provide approximate[ly] 56% of daily fiber intake, almost half of daily iron (3.5-fold more than non-baby foods), and 16% of zinc." Mot. Ex. 3, at 13 (Tobias Rep.). As Dr. Tobias explained, this study and others like it "clearly show[] that consuming more of these foods has more favorable neurodevelopmental outcomes in children later in life." Mot. Ex. 4, at 105:13–19 (Tobias Dep.). These opinions directly respond to Plaintiffs' experts' core theory that consuming Defendants' baby foods is harmful to neurodevelopment.

Dr. Tobias also provided a "heat map" to illustrate "the nutritional quality of [different baby food] products" and in support of her opinions that the diverse nutrients in those baby foods align

with dietary guidelines and recommendations—"particularly [the guidelines] for variety." Mot. Ex. 4, at 105:4–8 (Tobias Dep.). Dr. Tobias explained that the bases for this opinion include guidance from the U.S. Dietary Guidelines for Americans ("DGA"), the American Academy of Pediatrics ("AAP"), and the USDA emphasizing the importance of exposing infants to a variety of different healthy foods. *See, e.g.*, Mot. Ex. 3, at 7 (Tobias Rep.) (noting that "DGA recommends prioritizing foods that are rich in iron, zinc, calcium, iodine, fatty acids DHA and EPA, protein, and vitamins A, D, B6, B12, and folate from a variety of foods across all food groups"); *id.* at 11 (explaining that both AAP and USDA "underscore the importance of *variety* to ensure infants and toddlers receive the large number of key nutrients found across all food groups: fruits, vegetables, grains, protein foods, and dairy and fortified soy alternatives"). These opinions help to illustrate the flaw in Plaintiffs' experts' narrow focus on trace levels of heavy metals that may be present in these foods—namely, their total failure to acknowledge the scientific consensus that key nutrients found in baby foods play a critical role in healthy neurodevelopment.

Plaintiffs criticize Dr. Tobias for not considering whether the products in her heatmap had been tested for heavy metals and for not discussing those products' salt, sugar, and fat contents. Mot. at 28.[9] And they complain that Dr. Tobias did not assess the extent to which nutrients have mitigating effects on heavy metal absorption. *Id.* at 29. But whether Defendants' products may contain trace heavy metals or salt, sugar, and fat in no way undercuts Dr. Tobias's opinions that the overwhelming scientific consensus is that baby foods are a complex mixture containing key nutrients critical to neurodevelopment. Plaintiffs' experts, meanwhile, treat Defendants' products as nothing more than a source of low doses of heavy metals. Dr. Tobias's opinions help highlight why Plaintiffs' experts' failure to account for the diverse array of nutrients in those products and

[9] Plaintiffs also complain about the "process underlying [the] creation" of the heat map. *See id*. at 28 n.4. To be clear, Dr. Tobias selected over a hundred of Defendants' baby food products with two or more ingredients in order to represent the variety of these foods and demonstrate how they span the recommended nutrient-dense food groups and subgroups. Plaintiffs provide no explanation as to why Dr. Tobias's research or selection methods were somehow improper. Nor was Dr. Tobias required to "review internal company documents" when the same information was available through the methods she followed.

their net benefits renders their ultimate causation opinions unreliable.

2. Dr. Tobias's Opinions Are Reliable.

Plaintiffs also seek to exclude Dr. Tobias's assertion that her opinions "are in agreement with the findings of the scientific community generally that non-genetic causes of ASD are largely unknown; that there is no known post-natal cause of ASD," and that "the sparse and limited evidence does not establish that early life exposure to heavy metals causes or contributes to ASD or ADHD." Mot. at 29 (quoting Tobias Rep. at 5). Plaintiffs complain that Dr. Tobias is not qualified to offer such opinions because she (1) is not a geneticist, (2) did not perform a comprehensive review of non-genetic causes of ASD or ADHD, and (3) did not perform a comprehensive review of heavy metal exposure generally, or of whether it is associated with ASD or ADHD. Once again, these arguments miss the point.

First, Dr. Tobias cited numerous sources supporting her opinion regarding the lack of evidence for non-genetic, post-natal causes of ASD. *See, e.g.*, Mot. Ex. 4, at 19:21–20:22 (Tobias Dep.) (testifying that the bases of her opinion "is the American Academy of Pediatrics, for example, and other authoritative bodies on these disorders."); *id.* at 24:7-26:13 (testifying regarding USDA reviews on which she relied).

Second, Dr. Tobias's opinion is based on a reliable methodology. *See* Mot. Ex. 3, at 37–42 (Tobias Rep.). Specifically, Dr. Tobias conducted a systematic review of epidemiological literature on dietary heavy-metal exposures in order to investigate whether "exposures to heavy metals derived from a food or beverage source" can cause ASD. *Id.* at 37. Dr. Tobias's review did not identify any studies that established such an association—much less causation—between dietary heavy metal exposure and autism, with or without co-occurring ADHD. Dr. Tobias also conducted a literature review for studies on dietary heavy metal exposure and ADHD and concluded that there are ***no*** studies evaluating dietary exposures to lead or arsenic and ADHD. *Id.* at 39.

Plaintiffs criticize Dr. Tobias for failing to "perform a comprehensive systematic review of heavy metal exposure generally, or of whether it is associated with ASD or ADHD." Mot. at 29. But once again, the general-causation inquiry is not about heavy metals "generally" and whether

they can cause autism or ADHD. It is whether *consumption of Defendant's baby food products*—which, like all foods, may contain trace levels of heavy metals—is capable of causing those disorders. There was thus nothing unsound in Dr. Tobias analyzing whether there is any scientific evidence of an association between dietary heavy-metal exposure and autism/ADHD.[10] Indeed, as a nutritional epidemiologist, Dr. Tobias is well-qualified to perform such an analysis. Plaintiffs' attempts to exclude Dr. Tobias's opinions should be denied.

H. Dr. Filippelli's Opinion That the Significant Sources of Lead and Arsenic Exposure in Children Are Not Foods Is Relevant and Reliable.

Plaintiffs claim Dr. Filippelli's opinions do not "fit" the general causation inquiry because they do not address whether heavy metals can cause autism or ADHD. They also contend that his opinions regarding lead and arsenic are speculative and unreliable. Both arguments are meritless.

1. Dr. Filippelli's Opinions Fit the General Causation Inquiry.

Dr. Filippelli opines that the most substantial contributors to lead exposure in U.S. children are from sources such as soil and dust—***not*** baby food. Mot. Ex. 16, at 15–18 (Filippelli Rep.). Plaintiffs argue that this opinion is "irrelevant to general causation" and "lack[s] a valid connection to the pertinent inquiry." Mot. at 30 (citation and quotation marks omitted). Not so. Plaintiffs' experts opine that there is "no safe level" of exposure to lead. If that were accurate, it would mean that the soil and dust children are exposed to (a) months before they ever take their first bite of baby foods, (b) during the entire time they eat baby foods, and (c) after they stop eating baby foods, can cause autism or ADHD. Plaintiffs' experts ignore that children's exposure to lead primarily comes from sources other than the healthy fruits, vegetables, and grains they eat in baby food.

Plaintiffs further contend that Dr. Filippelli is not aware of the products or epidemiology at

[10] In any event, Dr. Tobias also reviewed recent meta-analyses on whether heavy metals are generally associated with autism/ADHD and concluded that they do not support such a finding. *See* Mot. Ex. 3, at 42 (Tobias Rep.) (stating that the meta-analyses present "major limitations of the overall evidence base to inform causal conclusions" and "underscore[] that conclusions for causality cannot be derived from the available evidence base when Bradford Hill criteria are appropriately applied.").

issue in this litigation, or specific heavy metal testing results, Mot. at 30–31, but none of these facts are pertinent or necessary to Dr. Filippelli's opinions. Plaintiffs also mischaracterize Dr. Filippelli's prior publications as inconsistent with his opinions. They are not. Dr. Filippelli has never concluded that postnatal lead exposure through any environmental source—particularly food—can cause autism or ADHD. The first publication, Laidlaw, et al. (2017), relates to lead exposure at firing ranges, and has nothing to do with exposures to lead in children through healthy food.[11] The second article, Filippelli and Laidlaw (2010), discusses the effects of lead poisoning, which is not an outcome at issue in this proceeding.[12]

Dr. Filippelli offers an alternative to Plaintiffs' experts' presumption that children's exposure to lead primarily comes from the healthy fruits, vegetables, and grains they eat in baby food. His opinions fit well within the scope of the general causation inquiry.

2. Dr. Filippelli's Opinions Regarding Substantial Contributors to Lead and Arsenic Exposure Are Reliable.

Plaintiffs also attack Dr. Filippelli's opinions on the grounds that "they lack sufficient facts and data and are therefore unreliable under Rule 702." Mot. at 32. These arguments fail because (1) Dr. Filippelli's opinions on substantial contributors to lead and arsenic exposure are based on his decades of experience in the field as well as scientific consensus; and (2) his opinion regarding the inverse relationship between autism rates and blood lead levels is based on unrefuted data.

a. Dr. Filippelli's Opinions Are Based on Decades of Experience and Scientific Consensus on the Substantial Contributors to Lead and Arsenic Exposure.

As noted above, Dr. Filippelli opines that the most substantial contributors to lead exposure in U.S. children are from environmental sources such as soil and dust, not baby food. Plaintiffs

[11] This article cites a single reference by different authors for the proposition that "elevated BLL's have been associated with . . . autism." This statement says nothing of the source or timing of any exposure to lead. And of course, "an association does not equal causation." *Reyes v. Apple, Inc.*, 2025 WL 1223550, at *8 (N.D. Cal. Apr. 28, 2025) (citation omitted).

[12] Notably, Plaintiffs neglect to mention that this article also identifies that inadequate nutrition "leads to soil pica behavior, as well as higher lead absorption rates due to iron deficiency anemia."

argue that this opinion is "speculative" because Dr. Filippelli has not done an in-depth review of heavy metals levels in baby food or compared lead exposure from baby food to lead exposure from environmental sources. Mot. at 32–33. Dr. Filippelli's opinion is based on a wide range of sources, none of which deem baby food a meaningful source of lead exposure in children. *See, e.g.*, Mot. Ex. 16, at 16 (Filippelli Rep.) (noting that the primary sources of lead exposure identified by the CDC include lead paint and pollution from cars and factories, but "commercial baby foods are not listed in the CDC's analysis"); *id.* at 22 ("[B]aby food is not included on CDC or EPA checklists for identifying and mitigating home-based lead sources, and with respect to food, the checklists focus on cookware and outlier foods like imported candies and spices.").

Moreover, Dr. Filippelli's opinions on lead exposure consider the levels of lead typically found in soil and paint versus baby food. *See id.* at 13 ("Natural levels of lead in U.S. soil, for example, range between 300 and 2,450,000 ppb (30 to 245,000 times higher than FDA's lowest action levels for certain baby food)."); *id.* at 14, 23. The same is true for arsenic exposure. *See id.* at 29 ("Soil naturally contains 2,000 to 5,000 ppb arsenic (20 to 50 times FDA's action level for infant rice cereal)"). As these examples demonstrate, exposure from media such as soil, dust, and paint are exponentially higher than those found in baby foods. Even the highest levels of metals found in Defendants' baby foods, which are measured in parts per *billion*, are miniscule in comparison to those exponentially higher levels for soil, dust and paint.

Plaintiffs nevertheless attempt to undermine Dr. Filippelli's opinions based on artificial "calculations" that Plaintiffs' counsel had him perform in his *Landon R.* deposition and again raised in Dr. Filippelli's MDL deposition. *See* Mot. at 33–34. Specifically, Plaintiffs' counsel asked Dr. Filippelli to make assumptions about lead and arsenic content in baby food (driven, in part, by the FDA's maximum levels of those metals in rice cereal) and compare the resulting calculations based on those figures to environmental exposure levels. Dr. Filippelli, while complying with Plaintiffs' counsel's math calculation requests, stressed that they were purely hypothetical and that he did not

accept Plaintiffs' underlying assumptions.[13] Defendants' counsel repeatedly objected to this artificial exercise.[14] Because these calculations were purely theoretical and had no connection to actual exposure data, they provide no basis to exclude Dr. Filippelli's opinions under Rule 702.[15]

b. Dr. Filippelli's Opinion Regarding the Inverse Relationship Between Autism Rates and Blood Lead Levels is Grounded in Unrefuted Data and Should Not Be Excluded.

Plaintiff attempts to exclude Dr. Filippelli's observation (supported by extensive data) regarding the significant rise of autism rates in the United States at the same time blood lead levels have plummeted. Neither of Plaintiffs' arguments for exclusion hold water.

Plaintiffs' first argument—that "Dr. Filippelli does not know if ASD rates are actually increasing or whether it is being caused by something else"—is premised on willful ignorance of the data and pure speculation. Plaintiffs do not dispute the data on autism rates set forth in Dr. Filippelli's report or that autism rates are "actually increasing." *See* Mot. Ex. 16, at 25–26 (Filippelli Rep.). Nor do Plaintiffs dispute that BLLs in U.S. children have significantly decreased over the past few decades. Mot. at 35. Rather, Plaintiffs assert that Dr. Filippelli failed to adequately account for confounders that would somehow explain why U.S. autism rates have been steadily increasing

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[13] *See, e.g.*, Mot. Ex. 35, at 106:12 (Filippelli *Landon R.* Dep.) (agreeing with result "only based on how you've done the calculation"); *id.* at 114:8–9 (noting that hypothetical calculation was based on factors chosen by Plaintiff's counsel); Mot. Ex. 17, at 81:3–7 (Filippelli Dep.).

[14] *See, e.g.*, Mot. Ex. 35, at 70:3-5, 75:11–13, 76:5–6, 81:6–8, 96:2–4; 97:7–9, 99:22–25 (Filippelli *Landon R.* Dep.); Mot. Ex. 17, at 80:19–81:2; 81:10–16; 81:20–82:10; 82:17-21 (Filippelli Dep.).

[15] Plaintiffs also takes issue with Dr. Filippelli's opinion that "commercial baby food does not put children at increased risk of arsenic exposure." Mot. at 34. Plaintiffs' entire quarrel with this opinion appears to be based on their claim that a CDC source cited by Dr. Filippelli does not support this opinion. However, Plaintiffs—without explanation—cite to a different portion of the CDC data ("Urinary Total Arsenic (creatinine corrected)") than Dr. Filippelli relied upon to support his opinion ("Urinary Total Arsenic") and about which he was questioned during his deposition. *Compare* Mot. Ex. 17, at 94:8–14 (Filippelli Dep.) ("And for years -- Exhibit 7, for the *urinary total arsenic, years 2011 to 2018*, and survey year 2017 to 2018, the total samples tested for urinary arsenic in the United States across all of these different populations was 2,792, correct? A: That's correct.") (emphasis added) *with* Mot. Ex. 36 (citing data based on "creatinine corrected" survey). Plaintiffs cannot misconstrue a document in an effort to undermine Dr. Filippelli's reliance on it—and such selective citation certainly does not furnish a basis for exclusion under Rule 702.

while BLLs in children have been markedly decreasing. But Dr. Filippelli took the possibility of such confounders into account in his analysis, and concluded that "[e]ven assuming some or most of the increase in autism prevalence was a result of changed diagnostic criteria, more careful screening, and other such reasons, the significant drop in blood lead levels fact is inconsistent with a hypothesis that consumption of lead from baby food is a cause of autism." *See* Mot. Ex. 16, at 25 (Filippelli Rep.).

Plaintiffs also fault Dr. Filippelli for failing to account for "other potential explanations" that they chose not to describe in their Motion but asked about in his *Landon* deposition. But the "other potential explanations" that Dr. Filippelli supposedly failed to consider were *Plaintiff's counsel's* speculative links between growing up in single-family homes and baby food consumption. Mot. Ex. 35, at 118:7–119:4 (Filippelli *Landon R.* Dep.). Rule 702 does not require Dr. Filippelli to account for or opine on such unfounded and speculative scenarios. Plaintiffs' motion to exclude Dr. Filippelli's opinions should be denied.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' Motion to Exclude Certain Testimony from Defendants' Expert Witnesses.

Dated: October 24, 2025

WILLIAMS & CONNOLLY LLP

By: /s/ *Neelum J. Wadhwani*
Joseph G. Petrosinelli (*pro hac vice*)
Neelum J. Wadhwani

WHITE & CASE LLP

By:/s/ *Bryan Merryman*
Bryan A. Merryman

Attorneys for Defendant Gerber Products Company

Dated: October 24, 2025

KING & SPALDING LLP

By: /s/ *Livia M. Kiser*
Livia M. Kiser
Michael Anthony Lombardo
Todd P. Davis (*pro hac vice*)

Attorneys for Defendants Beech-Nut Nutrition Company and Walmart Inc.

Dated: October 24, 2025

DLA PIPER LLP (US)

By: /s/ *Brooke Killian Kim*
Brooke Killian Kim
Mary Gately (*pro hac vice*)
Loren H. Brown (*pro hac vice*)

Attorneys for Defendant Nurture, LLC

Dated: October 24, 2025

COVINGTON & BURLING LLP

By: /s/ *Michael X. Imbroscio*
Michael X. Imbroscio (*pro hac vice*)
Phyllis A. Jones (*pro hac vice*)
David N. Sneed (*pro hac vice*)
Elizabeth T. Fouhey (*pro hac vice*)

Attorneys for Defendant The Hain Celestial Group, Inc.

Dated: October 24, 2025

GORDON REES SCULLY MANSUKHANI, LLP

By: /s/ *Michael R. Klatt*
Michael R. Klatt (*pro hac vice*)
Nancy Mae Erfle (*pro hac vice*)

Attorneys for Defendant Sprout Foods, Inc.

Dated: October 24, 2025

DECHERT LLP

By: /s/ *Hope S. Freiwald*
Hope S. Freiwald (*pro hac vice*)
Michelle H. Yeary (*pro hac vice*)

Attorneys for Defendant Plum, PBC

Dated: October 24, 2025

COZEN O'CONNOR

By: /s/ *Peter Michael Ryan*
Peter Michael Ryan (*pro hac vice*)
Joan M. Taylor (*pro hac vice*)
Brett Nicole Taylor

Attorneys for Defendant The Campbell's Company

CERTIFICATE OF SERVICE

I certify that on October 24, 2025, I electronically filed the foregoing DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN TESTIMONY FROM DEFENDANTS' EXPERT WITNESSES UNDER FRCP 26 AND FRE 702 using the ECF system, which sent notification of such filing to all counsel of record.

/s/ Neelum J. Wadhwani
Neelum J. Wadhwani